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- (74) Agents: ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343-9131 (US).

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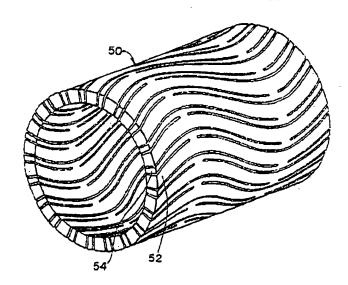
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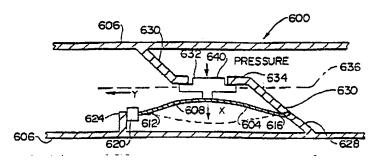
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(54) Title: BISTABLE SPRING CONSTRUCTION FOR A STENT AND OTHER MEDICAL APPARATUS

(57) Abstract

The present invention is directed to bistable cells and their use in devices, particularly medical devices such as stents, clamps and valves. An expandable stent formed of a plurality of bistable cells is described. The stent has two or more stable configurations, including a first stable configuration with a first diameter and a second stable configuration with a second, larger diameter. A valve comprising a bistable cell for use in eliminating incontinence is also disclosed.





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A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61F2/06 A61B A61B17/11 A61F2/00 F16K31/00 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) A61F A61B F16K F16L Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X WO 96 18359 A (FOUERE) 20 June 1996 1,11-13. 17-21. 28-33 see abstract; figures 1,2 X WO 95 09584 A (GUERBET) 13 April 1995 1,11-13,21, 28-33, 55-57 Υ see page 9, line 26 - page 10, line 12; 58 X WO 96 09013 A (WAKE FOREST INIVERSITY) 28 1,11-13,March 1996 30 - 33see abstract; figures 10,14 Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but "A" document defining the general state of the art which is not cited to understand the principle or theory underlying the considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention filing date cannot be considered novel or cannot be considered to "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention citation or other special reason (as specified) cannot be considered to involve an inventive step when the "O" document referring to an oral disclosure, use, exhibition or document is combined with one or more other such docu ments, such combination being obvious to a person skilled in the art. document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of theinternational search Date of mailing of the international search report 16.09*98* 4 September 1998 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk -Tel- (+31-70) 340-2040,-Tx: 31-651 epo nl; Neumann, E Fax: (+31-70) 340-3016

Int .tional Application No PCT/US 98/01310

C (Continue	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	PCT/US 98/01310
Category '		Relevant to claim No.
X	US 5 562 690 A (GREEN ET AL) 8 October 1996	1,54
A	see column 5, line 36 - column 7, line 13; figures 1-8	7,8
Ρ,Χ	US 5 695 516 A (FISCHELL ET AL.) 9 December 1997	1,9, 11-13, 15,16, 28-33
4	see the whole document	2-4
Ρ, χ	WO 97 04721 A (MEDSTENT) 13 February 1997	1,4, 11-13, 28-33
	see page 7, line 3 - line 33; figures 1,3,8-10	20 33
<i>(</i>	EP 0 587 197 A (ANGIOMED) 16 March 1994 see claim 7	58
Ą	US 5 234 448 A (WHOLEY ET AL.) 10 August 1993 see the whole document	7,8,54
1	WO 95 31945 A (SCIMED LIFE SYSTEMS) 30 November 1995	6
1	EP 0 326 426 A (JAPAN MEDICAL SUPPLY) 2 August 1989	
[WO 96 41589 A (COOK WILLIAM EUROP; KAVTELADZE ZAZA ALEXANDROVICH (RU); KORSHOK AL) 27 December 1996	51
	see page 16, line 10 - line 35; figures	37-39, 41-43, 46,47
	WO 93 22986 A (SCHNEIDER USA INC) 25 November 1993	51
	see page 13, line 16 - line 26	37-42,47
,	EP 0 688 545 A (TERUMO CORP) 27 December 1995	37-39, 41-43, 45,47,65
	see abstract; figures	75,47,05
	EP 0 364 787 A (EXPANDABLE GRAFTS PARTNERSHIP) 25 April 1990 see column 1, line 25 - line 50; figures	37-39,65
	-/	
		

In: Itional Application No PCT/US 98/01310

C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
ategory °		Relevant to claim No.
X	EP 0 664 107 A (NAZARI STEFANO) 26 July 1995 see column 3, line 44 - column 4, line 37; figures	52
X	US 4 994 071 A (MACGREGOR DAVID C) 19 February 1991 see column 3, line 54 - column 4, line 18; figures	52
(.	GB 2 081 173 A (BEHAR YVES;ALBERTINI PROSPER JEAN; GEFFROY JEAN LOUIS) 17 February 1982 see abstract; figures	52
4	US 3 508 587 A (MAUCH HANS A) 28 April 1970 see column 3, line 6 - line 48; figure 2A	52,53
(EP 0 734 698 A (VARIOMED AG) 2 October 1996 see the whole document	59
<i>t</i> .	EP 0 679 372 A (ADVANCED CARDIOVASCULAR SYSTEM) 2 November 1995 see figures	59
4	WO 96 03942 A (RAM MICHAEL J ;KALB IRVIN M (US); SHAW ROBERT H (US)) 15 February 1996 see page 10, line 14 - page 11, line 14; figures	66,67, 70,71
١	FR 2 642 812 A (CROUZET SA) 10 August 1990 see abstract; figures	66-68
1	EP 0 636 345 A (SENTINEL MEDICAL INC) 1 February 1995 see abstract; figures	66,70,71
\	US 3 069 125 A (J.C. HEWITT, JR.) 18 December 1962 see the whole document	66,68,69
(WO 96 29028 A (GRASS ANTHONY JAMES ;UNIV LONDON (GB); ADISESHIAH MOHAN (GB)) 26 September 1996 see page 3, paragraph 1 - paragraph 3; figures	73,74
\	see page 6, last paragraph - page 7, paragraph 2	75
	EP 0 744 164 A (COOK INC) 27 November 1996 see column 6, line 15 - line 37; figures see column 12, line 36 - line 42	73,74 75
	-/	

Int Itional Application No PCT/US 98/01310

.(Continu	Rtion) DOCUMENTS CONSIDERED TO BE RELEVANT	
ategory '	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to daim No.
	GB 2 169 515 A (LIFELINE LTD) 16 July 1986 see the whole document	73
1		74,75
(EP 0 421 729 A (MEDTRONIC INC) 10 April 1991 see abstract; figures	73,74
	US 5 141 360 A (ZEMAN DAVID) 25 August 1992	73-76
	see column 5, line 34 - line 68; figure 3	
A	WO 95 32757 A (NITINOL MEDICAL TECHNOLOGIES I) 7 December 1995 see abstract; figures	73-76
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International application No. PCT/US 98/01310

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: 48-50 60-64 72 because they relate to subject matter not required to be searched by this Authority, namely:
·	Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)
This Inte	mational Searching Authority found multiple inventions in this international application, as follows:
	see additional sheet
1. X	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-36, 54-58

A medical device containing at least one unit cell with one relatively flexible segment and one relatively rigid segment

1.1 Claims 1,2,5-29

A unit cell with symmetrical load-displacement

1.2 Claims 1,3,5-29

A unit cell with asymmetrical load-displacement characteristic, most stable in expanded state

1.3. Claims 1,4-29

A unit cell with asymmetrical load-displacement characteristic, most stable in collapsed state

1.4 Claims 30-36

A medical device with a multistable spring system

1.5 Claim 1.54

A clamp

1.6 Claims 55-58

A graft stent with expansion rings

2. Claims: 37-47,65

A stent with a negativ spring constant

3. Claim: 51

A stent with a plurality of diameters

4. Claims: 52, 53

An expandable device

5. Claim: 59

A stent with wavelike members

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

6. Claims: 66-71

A bistable valve

7. Claims: 73-77

A medical device with a cell with four rigid segments

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Information on patent family members

Int .tional Application No PCT/US 98/01310

		101/03	
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9618359 A	20-06-1996	FR 2728156 A AU 4119896 A EP 0843538 A	21-06-1996 03-07-1996 27-05-1998
WO 9509584 A	13-04-1995	FR 2710834 A AT 162065 T AU 7858594 A CA 2173500 A DE 69407984 D DE 69407984 T EP 0722304 A ES 2115262 T JP 9503141 T	14-04-1995 15-01-1998 01-05-1995 13-04-1995 19-02-1998 03-09-1998 24-07-1996 16-06-1998 31-03-1997
WO 9609013 A	28-03-1996	US 5702419 A AU 3418395 A CA 2200489 A	30-12-1997 09-04-1996 28-03-1996
US 5562690 A	08-10-1996	NONE	
US 5695516 A		NONE	
WO 9704721 A	13-02-1997	AU 6511196 A EP 0840578 A NO 980302 A PL 324781 A US 5776181 A	26-02-1997 13-05-1998 24-03-1998 08-06-1998 07-07-1998
EP 587197 A	16-03-1994	DE 9014230 U AT 107495 T DE 9116936 U DE 59102001 D DK 481365 T EP 0481365 A ES 2057709 T JP 4256759 A	21-11-1991 15-07-1994 01-09-1994 28-07-1994 07-11-1994 22-04-1992 16-10-1994 11-09-1992
US 5234448 A	10-08-1993	AT 156986 T CA 2090763 A,C CA 2173636 A	15-09-1997 29-08-1993 29-08-1993

Information on patent family members

In ational Application No PCT/US 98/01310

			· ·
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5234448 A		DE 69313162 D EP 0558352 A EP 0781528 A US 5254127 A	25-09-1997 01-09-1993 02-07-1997 19-10-1993
WO 9531945 A	30-11-1995	CA 2190012 A EP 0759730 A JP 10500595 T	30-11-1995 05-03-1997 20-01-1998
EP 326426 A	02-08-1989	JP 1192367 A JP 2561853 B CA 1307885 A DE 68920055 D DE 68920055 T US 4950258 A	02-08-1989 11-12-1996 29-09-1992 02-02-1995 11-05-1995 21-08-1990
WO 9641589 A	27-12-1996	AU 6121896 A EP 0836450 A	09-01-1997 22-04-1998
WO 9322986 A	25-11-1993	AU 693054 B AU 1905397 A AU 678350 B AU 3789793 A CA 2134090 A,C CA 2179668 A DE 9390115 U EP 0639958 A JP 2660101 B JP 7502673 T US 5645559 A	18-06-1998 19-06-1997 29-05-1997 13-12-1993 25-11-1993 09-11-1993 22-12-1994 01-03-1995 08-10-1997 23-03-1995 08-07-1997
EP 0688545 A	27-12-1995	JP 8000738 A JP 8196642 A JP 8215318 A	09-01-1996 06-08-1996 27-08-1996
EP 0364787 A	25-04-1990	AU 623438 B AU 4248589 A CA 1322628 A GR 3003987 T JP 2174859 A	14-05-1992 12-04-1990 05-10-1993 16-03-1993 06-07-1990

Information on patent family members

in ational Application No PCT/US 98/01310

•			
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0364787 A		JP 2680901 B US 5195984 A	19-11-1997 23-03-1993
EP 0664107 A	26-07-1995	IT 1269443 B US 5554183 A	01-04-1997 10-09-1996
US 4994071 A	19-02-1991	NONE	
GB 2081173 A	17-02-1982	FR 2487086 A DE 3127446 A JP 57052015 A	22-01-1982 06-05-1982 27-03-1982
US 3508587 A	28-04-1970	NONE	
EP 0734698 A	02-10-1996	DE 19512066 A DE 19540851 A AT 169484 T DE 19516191 A JP 9010318 A	28-11-1996 07-05-1997 15-08-1998 06-02-1997 14-01-1997
EP 0679372 A	02-11-1995	CA 2147709 A JP≆ -8126704 A US 5725572 A	26-10-1995 21-05-1996 10-03-1998
WO 9603942 A	15-02-1996	US 5476434 A AU 3320695 A CA 2195949 A CN 1159155 A EP 0793465 A JP 10507652 T US 5509889 A US 5704353 A	19-12-1995 04-03-1996 15-02-1996 10-09-1997 10-09-1997 28-07-1998 23-04-1996 06-01-1998
FR 2642812 A	10-08-1990	NONE	
EP 0636345 A	01-02-1995	AU 677061 B AU 6746894 A CA 2127637 A JP 7313520 A US 5562692 A	10-04-1997 02-02-1995 27-01-1995 05-12-1995 08-10-1996

Information on patent family members

In Itional Application No PCT/US 98/01310

		<u> </u>			
Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0636345	Α		US	5735815 A	07-04-1998
US 3069125	Α	18-12-1962	NONE		
WO 9629028	Α	26-09-1996	AU CA EP	5116896 A 2216522 A 0817599 A	08-10-1996 26-09-1996 14-01-1998
EP 0744164	Α	27-11-1996	AU CA JP US	5240596 A 2176987 A 9099095 A 5707376 A	19-12-1996 26-11-1996 15-04-1997 13-01-1998
GB 2169515	Α	16-07-1986	NONE		
EP 0421729	Α	10-04-1991	CA DE DE IE JP	2026604 A 69024901 D 69024901 T 73670 B 3151983 A	03-04-1991 29-02-1996 14-08-1996 02-07-1997 28-06-1991
US 5141360	A. e	. = .25=08 - 1992 -	US- US US	.5292073- A 5263791 A 5224796 A	08-03-1994 23-11-1993 06-07-1993
WO 9532757	A	07-12-1995	US CA EP JP US	5540712 A 2191307 A 0788390 A 10504200 T 5746765 A	30-07-1996 07-12-1995 13-08-1997 28-04-1998 05-05-1998